Remarks

Claims 70-79 have been indicated to be allowable but are under consideration for the declaration of an interference. Since the prospective interference may delay the prosecution and issuance of the other claims under consideration in this application and since no decision on the interference has yet been made, claims 70-79 have been canceled from the application without prejudice to their presentation in continuing applications.

Claims 1-3, 6-8, 12, 13, 37, 38, 40, 42-48, 50, 51 and 63-69 have been rejected under 35 USC 103 as being unpatentable over Demeter in view of Dulebohn.

With respect to claims 1, 2 and 69, the applicants respectfully traverse the rejection. The rejection states that a person skilled in the art would have found it obvious to substitute the material used in Dulebohn in the device of Demeter in order to provide a device which was stronger and more elastic.

However, as set forth in claim 1, the applicants' invention is not about a mere substitution of one material for another but rather that the invention requires that the device have a construction which utilizes the pseudoelasticity of the material during its operation. In particular, claim 1 states that "... the arrangement being such that the at least one alloy member bend(s) or twist(s) pseudoelastically in a lateral or helical sense to manipulate the matter ..."

Pseudoelasticity is a special property of shape memory alloys. It is by definition a material state that is beyond the normal elastic range of a material. This is set forth in some detail in the "substitute specification" at page 3, line 19 to page 4, line 33. When subjected to stress, a conventional material will have a range over which the material will elastically deform. The elastic deformation is reversible in that releasing the stress will allow the material to return to its original shape. If one goes beyond the stress of elastic deformation for the material, the material will be plastically deformed and will not return to its original shape. A shape memory alloy has a range of stresses for which it will undergo elastic deformation and a range of stresses for which it will undergo plastic deformation. But it also has a range of stress over which the deformation is pseudoelastic. The pseudoelasticty can be depicted graphically as shown Figure 2 of U.S. Patent 4,665,906 to Jervis, which is mentioned in the specification. A copy of Figure 2 is attached for the Examiner's convenience. The Jervis patent describes this figure as follows:

> In FIG. 2, when a stress is applied to the alloy, it deforms elastically along line OA, then by SIM along line AB, and by deformation of the martensite to point C, just as in FIG. 1. However, the stress-strain behavior on unloading is significantly different, since the alloy is above As and the stable phase is therefore austenite.

> As the stress is removed, the alloy recovers elastically from C to D; then, at a critical stress, σA, the alloy reverts to austenite without requiring a change in temperature. Thus reversion occurs at essentially constant stress. Finally if the stress is removed from the reverted austenite, it recovers elastically along line EO. The recoverable deformation associated with the formation and reversion of stress-induced martensite has been referred to as pseudoelasticity.

Therefore, the applicants' device is one which is designed to use the pseudoplastic range of this material. That is, during normal operation of the device, the device responds to the application of stress by pseudoelastic deformation along line AB and then responds to the release of stress by recovery along line CD. However, there is nothing in the design of the device of Demeter that would require it to operate in this range. In Figure 1, the struts holding the pocket-shaped sheath are shown to substantially follow the axis of the device with a proximal end that runs along the axis of the device and then flares outward toward the distal end. In Figure 6, the struts are shown as they have been folded inward and drawn into the outer catheter. They are not shown to be compressed so tightly that an ordinary metal spring material would not suffice. In fact, no criticality is indicated in the discussion of the materials used for the struts at column 4, lines 42-57. Compare this with the device shown in the applicants' drawing figures 3-3 to 3-6 in which the a high degree of elasticity is plainly required in order to allow the basket to spring fully open as it is deployed and then to close and return into the catheter in order to retrieve the object. The sharp bends shown would not be expected to spring fully open with conventional materials since they would have been plastically deformed when loaded into the catheter. This same argument regarding the limit of elasticity is also made in the Dulebohn reference at column 5, lines 9-23 for the limits of bending for the loop of wire used in its snaring device.

With respect to the Dulebohn reference, this snare is also designed such that it can use conventional surgical wire. The wire is formed as a gentle loop without any sharp bends which could suffer deformation as the wire is pulled into the catheter. Also, as shown particularly well in Figures 10-11 of the Dulebohn reference, the wire loop is protected from deformation exceeding its limit of elasticity by a engaging with a rounded portion of minimum radius at the tip of the catheter as the wire is pulled fully into the catheter. The use of shape memory wire is only indicated at column 5, lines 61-66 as being used to make even smaller loop ends on the catheter. It is not indicated to be useful for the purpose of causing a pouch or other receptacle to spring open as it is used in the applicants' invention or as in the device of the Demeter reference. Therefore, Demeter and Dulebohn are not properly combinable and even if combined, they do not contain the elements requisite to make the applicants' invention. Therefore, the invention as set forth in claims 1-2 are patentable over the rejection and the rejection should be withdrawn.

With respect to claims 3, 6-8, 63-65 and 68 claims 3, 63, 65 and 68 have been canceled and claim 6 has been rewritten in independent form. Claims 7, 8 and 64 now depend from claim 6. The same reasons for allowance of claims 1-2 above also apply to

amended claims 6-8 and 64. Claim 6 recites that the shape memory alloy works in the superelastic or pseudoelastic region during the operation of the device -- that is, that the transition between austenite and martensite is accomplished during the normal operation of the device in deploying and withdrawing the distal end out of and into the bore of the cannula. Therefore, for the same reasons as set forth above, claims 6-8 and 64 are patentable over the grounds for rejection.

With respect to claims 12 and 13, those claims are believed to be included in the prosecution of a related application (Serial No. 08/022,259) which is still pending. Accordingly, claims 12 and 13 have been canceled from this application in favor of their prosecution in the other application.

With respect to claims 37-38, those claims have been amended to indicate that the loop is made from a pseudoelastic material and that the loop is pseudoelastically expanded as the device is advanced from a compressed to an uncompressed state. Thus, claims 37-38 also require that during the operation of the device that the device is designed to spring open by the use of the pseudoelastic properties of the loop material. This also clearly distinguishes the device from the Demeter and Dulebohn references as set forth above. Claims 37-38 are therefore also patentable over the grounds for rejection.

With respect to claims 40, 42-43 and 66-67, the claims have been amended to indicate that the wire of shape memory alloy includes stress induced martensite when the wire is constrained within the housing. The presence of stress induces martensite in the constrained wire allows the wire to expand pseudoelastically as the constraint of the housing on the wire is released. Thus, claims 40, 42-43 and 66-67 also require that during the operation of the device that the device is designed to spring open by the use of the pseudoelastic properties of the loop material. This also clearly distinguishes the device from the Demeter and Dulebohn references as set forth above. Claims 40, 42-43 and 66-67 are therefore also patentable over the grounds for rejection.

With respect to claims 44-47, the claims have been amended to include a member comprising a pseudoelastic material with the pseudoelastic member constrained within the housing such that it expands pseudoelastically into an expanded shape when the surgical screen is moved between the constrained and unconstrained positions. Thus, claims 44-47 also require that during the operation of the device that the device is designed to spring open by the use of the pseudoelastic properties of the material used in its construction. This also clearly distinguishes the device from the Demeter and Dulebohn references as set forth above. Claims 44-47 are therefore also patentable over the grounds for rejection.

With respect to claims 50-51, the claims have been amended to include a pseudoelastically deformable member which is constrained within the housing and expands pseudoelastically into an expanded shape when the retractor is moved between the first position and the second position. Thus, claims 50-51 also require that during the operation of the device that the device is designed to spring open by the use of the

pseudoelastic properties of the material used in its construction. This also clearly distinguishes the device from the Demeter and Dulebohn references as set forth above. Claims 50-51 are therefore also patentable over the grounds for rejection.

Reconsideration and allowance of all claims, as amended, is respectfully requested.

Respectfully submitted,

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